REMARKS

Claims 34-42 currently appear in this application. The Office Action of October 31, 2003, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Applicant's attorney wishes to thank Examiner Wortman for the courtesies extended during the telephone interview of December 17, 2003.

As claims 19-33 have been cancelled, it is respectfully submitted that the rejections of claims 19-33 in the Office Action of October 31, 2003, are now moot.

Entry and consideration of the present amendment are respectfully requested, as the present amendment does not raise any new issues. New claims 34-42 are claims 21, 23, 24, 25, 27, 31 and 33 rewritten to claim only the use of the two compounds, etanercept, and infliximab.

It is respectfully submitted that the specification as filed enables one skilled in the art to use the herein claimed invention, as required by *in re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The present inventors discovered that inhibiting the effects of TNF-alpha is effective in

treating hepatitis. In the present claims, the compounds that inhibit the effects of TNF-alpha are etanercept and infliximab, both of which are compounds which have been found to be effective in treating rheumatoid arthritis by neutralizing the activity of secreted TNF. Since both etanercept and infliximab are compounds which have historically been used to treat rheumatoid arthritis, one skilled in the art could readily determine a dosage of either of these compounds that would be useful in treating hepatitis.

For example, as noted in the MPEP Section 2164.01(c), it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph.

Etanercept and infliximab both work by neutralizing the activity of secreted TNF-alpha. Therefore, a physician who is familiar with dosages of etanercept or infliximab for treating rheumatoid arthritis by neutralizing the effects of TNF-alpha would be able to administer an amount of etanercept

or infliximab sufficient to neutralize the effects of TNF-alpha.

The inventors, in their declaration submitted with the amendment filed July 18, 2003, note that there have been numerous studies indicating that the cytokine system plays an important role in eth pathogenesis of hepatitis C infection with respect to both severity and chronicity. The hepatitis C virus has been reported to induce TNF-alpha gene expression and TNF-alpha itself. In addition, TNF-alpha has been shown to induce hepatitis when injected into humans and rodents. Thus, one skilled in the art of administering compounds that neutralize the effects of TNF-alpha, would be able to determine effective dosage and method of administration of the two known compounds claimed in the method of the present invention.

In response to the Examiner's concern that only one example is given, it should be noted that there is no requirement for any examples if one skilled in the art can practice the invention without undue experimentation. The present inventors have demonstrated that neutralizing the effects of TNF-alpha was successful in treating a patient with hepatitis. As this example illustrates that the treatment, administering a TNF-alpha inhibitor, was effective in treating a patient suffering from hepatitis, it should suffice to

demonstrate that the invention works. There is no requirement to conduct controlled studies such as are required for a New Drug Application.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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